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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,003	09/25/2001	Giuseppe Scala	15280-3862US	6807

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EXAMINER	
STUCKER, JEFFREY J	

ART UNIT	PAPER NUMBER
1648	14

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
Examiner	Group Art Unit	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 6/26/03 & 9/9/03.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☐ Claim(s) 1-23 is/are pending in the application.

Of the above claim(s) 3, 4, 6, 8, & 11-23 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) 1, 2, 5, 7, 9, & 10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The proposed drawing correction, filed on 9/9/03 is ☒ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachm nt(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing R view, PTO-948

☐ Other _____

Office Acti n Summary

This Office Action is in response to the amendment filed 26 June 2003.

The drawings filed 09 September 03 have been approved by the draftsman.

Applicant's arguments concerning examining claims 5 and 9 have been persuasive and these claims have been rejoined. Claims 11-23 remain withdrawn from consideration as being directed to non-elected inventions. Claims 3, 4, and 8 are withdrawn from consideration because they lack the elected invention. Claims 1, 2, 5, 7, 9, and 10 are examined and under final rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

It is noted that the amendment to claim 1 apparently added "SEQ ID NO:31" which was not in the original claim, is not indicated as being newly added and has not been examined and will not be examined except to the extent that elected SEQ ID NO: 1 reads on it.

The amendment to claim 9 canceled the sequence number, which should have not been canceled.

The objection to claims 1 and 6 for containing non-elected peptides is withdrawn in view of the amendment to the claims.

The rejection of claim 7 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claim.

The rejection of claim 10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

In claim 10, it is not clear what is meant by "does not give rise to HIV-1 specific antibodies to more than twelve other antigenic determinants on HIV-1". It is not apparent that this further limits the claimed invention as this is a quality of the antigenic peptide.

Applicant argues that element in question is a functional element in which the antigenic peptide which has this claimed sequence also has this characteristic feature and appropriately modifies the invention. This is not deemed to be persuasive because one not know the metes and bounds of the claimed invention due to the immense variation in viral strains due to a very high rate of mutation. One certainly could not know at any

given time all of the existing sequences of HIV-1 as they are continuously evolving. Therefore, one would not know if antibodies are specific to no more than twelve other antigenic determinants.

The rejection of claims 1, 2, 7, and 10 under 35 U.S.C. § 101 because the invention as disclosed is inoperative and therefore lacks patentable utility. The rejection of the antigenic composition, claims 1, and 2 are withdrawn in view of the arguments. The rejection is maintained against the vaccine claims.

Claims 5 and 9 are added to this rejection in view of applicant's arguments concerning rejoining these claims with the elected invention. The same rejection can be applied to these claims as to claim 7 for the same reasons and would not change the rejection or the response.

The rejection of claims 5, 7, and 9 under 35 U.S.C. § 101 because the invention as disclosed is inoperative and therefore lacks patentable utility is maintained.

Applicant argues that the claimed peptides can be used to stimulate B cells and purify antibodies and that the peptides are immunogenic. The specification is purported to define a vaccine as a composition that elicits an immune response that is anti viral.

These arguments are persuasive to the extent that an antigenic peptide stimulates an immune response that may produce antibodies that bind to a specific peptide or protein but is not persuasive in regards to a vaccine. The immune response produced by a vaccine must be more than merely some immune response but must be protective. As noted in the previous Office Action, the art recognizes the term "vaccine" to be a compound which prevents infection. Applicant has not demonstrated that the instantly claimed vaccine meets even the lower standard set forth in the specification, let alone the standard art definition, for being operative in this regards. Therefore, claims 5, 7, and 9 are not operative as an anti-HIV-1 vaccine and therefore lack patentable utility.

The rejection is also maintained on claim 10. Applicant argues that because this claim recites both a structural characteristic as well as a functional characteristic, it meets the written description requirement. This is not convincing as the specification has not described the scope of the claimed invention. Specifically, the disclosure does not describe the claimed invention because one could not possibly know at any given time all of the existing sequences of HIV-1, as they are continuously evolving. Therefore, the specification could not disclose peptides which induce antibodies that are specific to no more than twelve other antigenic determinants.

The rejection of claims 1, 2, 5, 7, and 9 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antigenic composition, does not reasonably provide enablement for a vaccine which protects against HIV-1 is maintained.

Applicant argues that the specification defines a vaccine composition as one that elicits an immune response that is anti-viral and is not required to completely protect an individual from HIV-1 infection and the peptides have been asserted to elicit antibody responses *in vivo* which should be sufficient to enable the invention. Applicant further argues that the specification teaches how to use the peptides directly and indirectly as diagnostic reagents.

The later point is not convincing because the claims are not directed to immunoassay reagents or methods of producing immunoassay reagents but to vaccines and immunogenic compositions for vaccinating against HIV-1 infection.

The former point is not convincing. Assuming that humans, the host for HIV-1, produce antibodies in response to the claimed peptide, it does not follow that the response is sufficient to meet even the specification's definition, let along the art recognized standard. As noted in Paul in the previous Office Action, there is not always a correlation between seroconversion and protection from disease. Given the teachings in the art, it is clear that a compound that merely

induces an immune response is not sufficient but must be protective to qualify as a vaccine. See at the top of page 1312: "[T]here was not always a correlation between sero-conversion and protection from disease...." In other words, the production of antibodies is not equivalent to anti-viral effect. Applicant has not taught how to use the instantly claimed peptide to induce an anti-viral effect. Therefore, the instant application is not enabled for antigenic peptides or vaccines which protect against HIV-1.

The following is a new ground of rejection necessitated by applicant's amendment:

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 lacks an antecedent basis for "selected from the group consisting of" as there is no group.

No claims are allowed.

Applicant's amendment necessitated the new ground of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm. After 28 January 2004, the phone number will be (571)-272-0911.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center Customer Service representative whose telephone number is (703) 308-0198.

Jeffrey Stucker

JEFFREY STUCKER
PRIMARY EXAMINER